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REMARKS

Applicant appreciates the time taken by the Examiner to carefully review Applicant's present application. At the time of the Office Action mailed July 17, 2006, Claims 1-223 were pending in this Application and were rejected. Claims 1, 6, 10, 17, 19 and 20 have been amended. Claims 4 and 5 have been cancelled. New Claims 24-34 have been added to further define the present invention. Applicants respectfully request reconsideration and favorable action in this case.

Replacement Declaration

The Office Action identifies deficiencies related to the present declaration. A supplemental declaration is submitted herewith.

Claim Objections

Claims 1, 17 and 20 were objected to for informalities. Applicant has amended Claims 1, 17 and 20 to address the aforementioned informalities.

Rejections under 35 U.S.C. § 112

Claims 19-23 were rejected under 35 U.S.C. 112 as being indefinite. Claim 19 has been amended to correctly identify its dependency from Claim 18. Applicants request reconsideration and withdrawal of the §112 rejections to Claims 19-23.

Rejections under 35 U.S.C. § 102

Claims 1, 4, 5, 7, 17 and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,915,688 granted to Bischof et al. ("Bischof"). Applicant respectfully traverses.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1997).

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Independent Claims 1 and 17 each recite an <u>implant material</u> injection system. Further, Independent Claims 1 and 17 each recite, among other limitations, a <u>remote</u> actuation component.

Bischof does not disclose a system for injecting an implant material.

The Bischof reference is directed to "a valve for the administration and/or production of medicines and nutrient solutions..." Col. 1, lines 7-8. In particular, Bischof contemplates a device for the infusion of "parenteral multi-nutrient solution, an electrolyte, bicarbonate, gamma globulin, fat, blood lidocain (for heart stabilization), etc." Col. 2, lines 11-14. Accordingly, Bischof does not provide any disclosure, teaching or suggestion of a system for injecting implant material as recited. As is well known, implant material such as Polymethylmethacrylate has a much lower viscosity than the infusion fluids contemplated by Bischof and one of skill in the art would clearly recognize that the device taught by Bishcof would not be suitable for injecting low viscosity fluids such as implant materials.

Accordingly, Applicant submits that Bischof fails to disclose, teach or suggest a system for injecting <u>implant material</u> as recited in Claims 1 and 17.

Bischof does not disclose a <u>remote</u> actuation device.

The Bischof reference includes a multi-way valve that includes an injection site (connection piece 34) for injecting a drug via a syringe 38. See Fig. 1 and Col. 3, lines 52-53. The office action contends that syringe 38 "comprises a means for remote actuation." Office Action, page 4. Applicant respectfully disagrees. First, syringe 38 is inserted directly into connection piece 34 in the conventional manner, and cannot said to be "remote" with respect to the multi-way valve of Bischof. Second, the office action contends that supply bag element 20 is a "separate container." See Office Action appended figure, page 10. However, if supply bag 20 is considered to be a "separate container", as argued in the office action, nonreturn valve '36 would prevent syringe 38 and its plunger from being "adapted to draw implant material from the separate container into at least a portion of a chamber" as recited in Claim1, as amended.

For at least these reasons Applicant submits that Bischof does not disclose, teach or suggest each and every element of the Claims 1 and 17. Applicant submits that Bischof clearly

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cannot anticipate Claims 1 and 17. Applicant requests reconsideration, withdrawal of the rejections under §102 and full allowance of Claims 1 and 17 and Claims 7 and 18 that depend therefrom.

Rejections under 35 U.S.C. §103

Claims 2, 3, 6, 8-16 and 19-23 were rejected under 35 U.S.C. 103 as being obvious over Bischof in view of U.S. Patent 5,376,094 granted to Kline et al. ("Kline"). Applicants respectfully traverse this rejection.

According to the Manual of Patent Examining procedure:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Manual of Patent Examining Procedure, § 2143.

The Bischof reference is discussed above. The Kline reference is cited for disclosing a particular configuration of actuator.

The Kline Reference

The Kline reference is directed to a surgical device including a "working element" and an actuating member. See Col. 1, lines 58-62. The working elements contemplated by Kline include a snare loop and "baskets 66-78, grasping forceps 80, right angle snare loop 82, or point type cauterization device 90..." Col. 6, lines 4-7 and Figures 8-19.

Claims 2, 3, 6 and 8-10 depend from Claim 1. As discussed above, Bischof fails to disclose, teach or suggest a system for injecting implant material. The Kline reference also does not teach a system for injecting implant material.

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Independent Claim 11 is directed to a system for injecting <u>implant material</u>. Independent Claim 18 is directed to a method for delivering <u>flowable implant material</u>.

The office action contends:

"It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the implant material injection system of Bischof et al. with the actuator having first and second grip portions, in order to give the handle good fidelity (column 1, lines 28-31); and a cable set with a housing connecting the actuator and the pressure driver, in order to move the piston and create a suction in the pressure driver and allow for withdrawal of the fluid (column 6, lines 32-34).

Office Action, page 5.

Applicant submits that the above contention is insufficient to establish a prima facie case of obviousness for a number of reasons. First, as discussed above, Bischof is not directed to an implant material injection system as contended. Second, the cited portion of Klein recites: "It is desirable that a snare handle have great fidelity so that whatever resistance is experienced by the snare is felt through the handle by the operator." Col. 1, lines 28-32. Emphasis Added. Clearly, desirability for fidelity of Kline cited in the Office Action pertains to use with a snare device and does not provide any motivation for application with respect to the fluid delivery device of Bischof. Third, there is no motivation for including the remote actuator of Bishof to move the piston of syringe element 38 of Bischof (that the Office Action argues acts as a "remote actuator".) Simply put, neither Bischof nor Kline provides any disclosure, teaching or suggestion that remote actuation is desirable for the Bischof device. It would appear that the multiway valve of Bischof would be readily accessible such that a typical syringe may be used to directly access the injection site 36 and that there would be no need or desirability for including a remote actuator as disclosed by Kline.

For at least these reasons Applicant submits that Bischof and Kline cannot render obvious any of Claims 2, 3, 6, 8-16 and 19-23. Applicant requests reconsideration, withdrawal of the rejections under §103 and full allowance of Claims 2, 3, 6, 8-16 and 19-23.

New Claims

New Claims 24-34 have been added to further define the present invention. Applicant submits that New Claims 24-34 are allowable over the cited art.

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CONCLUSION

Applicant has made a sincere effort to address all issues raised in the Office Action. If the Examiner believes a telephone conference would expedite prosecution of this application, a telephone call to the undersigned attorney at the number listed below will be appreciated.

Respectfully submitted,

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